185a

14

No. 05-608

Supreme Court, U.S.
FILED
JUL 26 2006
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.

Petitioner,

v.

GENENTECH, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICI CURIAE THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK, THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, THE AMERICAN ASSOCIATION OF MEDICAL COLLEGES, THE ASSOCIATION OF AMERICAN UNIVERSITIES AND OTHERS SUPPORTING RESPONDENTS

TERESA M. CORBIN
JENNIFER A. SKLENAR
HOWREY LLP
525 Market Street, Suite 3600
San Francisco, CA 94105
(415) 848 4900

JERROLD J. GANZFRIED
Counsel of Record
JOHN F. STANTON
HOWREY LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 783-0800

RICHARD G. TARANTO
FARR & TARANTO
Suite 800
1220 19th Street, N.W.
Washington, DC 20036-2435

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20001

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTEREST OF AMICI CURIAE 1

INTRODUCTION AND STATEMENT OF THE CASE .. 2

SUMMARY OF ARGUMENT 6

ARGUMENT 8

I. A Licensee's Continuing, Voluntary Performance Of Its Agreement To Pay Patent Royalties Bars Article III Jurisdiction Over The Licensee's Declaratory Judgment Challenge To The Patent's Validity, Enforceability, Or Coverage 8

A. Traditional Article III Standards Preclude Jurisdiction 8

B. Federal Law Respects the Licensor's Repose While the Licensee is Sheltered by the License 14

1. *Lear* Does Not Authorize a Challenge to Patent Validity in These Circumstances 14

2. Federal Patent Law Should Respect, Not Preempt, License Agreements Like MedImmune's 19

3. The Policy Considerations are Reinforced in the University Setting By the Bayh-Dole Act 20

II. Even If Medimmune's Suit Presented A Case Or Controversy, It Seeks Equitable Relief That

Should Be Categorically Unavailable Under The Declaratory Judgment Act 23

CONCLUSION 30

TABLE OF AUTHORITIES

Page(s)

CASES

AirLine Pilots Ass'n, International v. O'Neill,
499 U.S. 65 (1991) 17

Ake v. Oklahoma,
470 U.S. 68 (1985) 13

Albemarle Paper Co. v. Moody,
422 U.S. 405 (1975) 24

Allen v. Wright,
468 U.S. 737 (1984) 8, 9

Altvater v. Freeman,
319 U.S. 359 (1943) 6, 9

Aro Corp. v. Allied Witan Co.,
531 F.2d 1368 (6th Cir. 1976) 18

Aronson v. Quick Point Pencil Co.,
440 U.S. 257 (1979) 16, 17

Babbitt v. United Farm Workers National Union, 442 U.S. 289 (1979) 25

Bement v. Nat'l Harrow Co.,
186 U.S. 70 (1902) 19

Buckley v. Airshield Corp.,
977 F. Supp. 375 (D. Md. 1997) 20

C.R. Bard, Inc. v. Schwartz,
716 F.2d 874 (Fed. Cir. 1983) 28

TABLE OF AUTHORITIES—Continued

Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992) 12

City of Los Angeles v. Lyons,
461 U.S. 95 (1983) 11

Coleman v. Thompson,
501 U.S. 722 (1991) 13

Cont'l Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405 (1908) 19

DaimlerChrysler Corp. v. Cuno,
126 S. Ct. 1854 (2006) 8

De Forest Radio Telegraph Co. v. United States, 273 U.S. 236 (1927) 11

Dura Pharmaceuticals., Inc. v. Broudo,
544 U.S. 336 (2005) 11

eBay Inc. v. MercExchange, L.L.C.,
126 S. Ct. 1837 (2006) 20

Eccles v. Peoples Bank of Lakewood Village, 333 U.S. 426 (1948) 23

Enterprise Irrigation District v. Farmers Mutual Canal Co., 243 U.S. 157 (1917) 13

Ford Motor Co. v. EEOC,
458 U.S. 219 (1982) 24

Foster v. Hallco Manufacturing Co.,
947 F.2d 469 (Fed. Cir. 1991) 20

TABLE OF AUTHORITIES—Continued

Gen-Probe Inc. v. Vysis, Inc.,
359 F.3d 1376 (Fed. Cir.),
cert. dismissed, 543 U.S. 941 (2004) 4

Golden v. Zwickler,
394 U.S. 103 (1969) 25

Herb v. Pitcairn,
324 U.S. 117 (1945) 13

Illinois Tool Works, Inc. v. Independent Ink, Inc., 126 S. Ct. 1281 (2006) 16

Kelly v. Kosuga,
358 U.S. 516 (1959) 28

Lear, Inc. v. Adkins,
395 U.S. 653 (1969) ..... *passim*

Local 28 of the Sheet Metal Workers' International Ass'n v. EEOC,
478 U.S. 421 (1986) 24

Louisville & Nashville Railroad v. Woodford, 234 U.S. 47 (1914) 13

Lujan v. Defenders of Wildlife,
504 U.S. 555 (1992) 9

Martin v. Franklin Capital Corp.,
126 S. Ct. 704 (2005) 24

McConnell v. FEC,
540 U.S. 93 (2003) 9

Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270 (1941) 10

TABLE OF AUTHORITIES—Continued

MedImmune, Inc. v. Centocor, Inc., No. AW-02-1135, 2004 U.S. Dist. LEXIS 28800 (D. Md. June 17, 2004), *aff'd*, 409 F.3d 1376 (Fed. Cir. 2005) 4

MedImmune, Inc. v. Centocor, Inc., 271 F. Supp. 2d 762 (D. Md. 2003), *aff'd*, 409 F.3d 1376 (Fed. Cir. 2005) 3, 4

MedImmune v. Centocor, 409 F.3d 1376 (Fed. Cir. 2005) ..... *passim*

Public Affairs Associates, Inc. v. Rickover, 369 U.S. 111 (1962) 23

Quick Point Pencil Co. v. Aronson, 425 F. Supp. 600 (E.D. Mo. 1976) 16

Steffel v. Thompson, 415 U.S. 452 (1974) 6, 9

U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership, 513 U.S. 18 (1994) 24, 26

U.S. National Bank of Oregon v. Independent Insurance Agents of America, 508 U.S. 439 (1993) 8

United Public Workers v. Mitchell, 330 U.S. 75 (1947) 8

United States v. Criden, 648 F.2d 814 (3d Cir. 1981) 25

Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc., 126 S. Ct. 980 (2006) 26

Vermont Agency of Natural Resources v. U.S. ex rel. Stevens, 529 U.S. 765 (2000) 13

Whitmore v. Arkansas, 495 U.S. 149 (1990) 10

Wilton v. Seven Falls Co., 515 U.S. 277 (1995) 23, 24

Yakus v. United States, 321 U.S. 414 (1944) 26

Younger v. Harris, 401 U.S. 37 (1971) 25

Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100 (1969) 19

STATUTES

28 U.S.C. § 1257 13

28 U.S.C. § 2201(a) 4

35 U.S.C. §§ 301-307 ..... 11, 17

COMMENTATORS

Edwin Borchard, DECLARATORY JUDGMENTS (1941) 23, 26-27

Rochelle Cooper Dreyfuss, *Dethroning Lear: License Estoppel and the Incentive to Innovate*, 72 VA. L. REV. 677 (1986) 16, 18

Richard H. Fallon, Jr., et al. HART AND WECHSLER'S FEDERAL COURTS AND THE FEDERAL SYSTEM (4th ed. 1996) 13

Nellie A. Fisher, *The Licensee's Choice: Mechanics of Successfully Challenging a Patent Under License*, 6 TEX. INTELL. PROP. L.J. 1 (1997) 28

Henry J. Friendly, *Indiscretion About Discretion*, 31 EMORY L.J. 747 (1982) 24

Emmette F. Hale, III, *The "Arising Under" Jurisdiction of the Federal Circuit: An Opportunity for Uniformity in Patent Law*, 14 FLA. ST. U. L. REV. 229 (1986) 20

Note, *Patent Licensee Standing and the Declaratory Judgment Act*, 83 COLUM. L. REV. 186 (1983) ..... *passim*

John W. Schlicher, *A Lear v. Adkins Allegory*, 68 J. PAT. & TRADEMARK OFF. SOC'Y 427 (1986) 18

John W. Schlicher, LICENSING INTELLECTUAL PROPERTY: LEGAL, BUSINESS, AND MARKET DYNAMICS (1996) 11, 27

Kim R. Smith, *Foreclosure of License Validity Challenges with Procedural Barriers: Federal Jurisdiction*, 61 J. PAT. OFF. SOC'Y 690 (1979) 11

Mary Margaret Styer, et al., *A Guide Through the Labyrinth: Evaluating and Negotiating a University Technology Transfer Deal*, 11 B.U. J. SCI. & TECH. L. 221 (2005) 1

William C. Rooklidge, *Licensee Validity Challenges and the Obligation to Pay Accrued Royalties: Lear v. Adkins Revisited (Part II)*, 69 J. PAT. & TRADEMARK OFF. SOC'Y 5 (1987) 15, 16

4 PAT. L. PERSP. (MB) § 6.2[2.-2] (2d ed. 2005)..... 28

7 PAT. L. PERSP. (MB) § 12.4[6] (2d ed. 2005)..... 19, 20, 29

INTEREST OF AMICI CURIAE[1]

Amici and their member universities are non-profit academic institutions that invest significant resources in the scientific research of their faculty, staff and students.[2] The Bayh-Dole Act (P.L. 96-517, Patent and Trademark Law Amendments Act of 1980) encourages such institutions to obtain patent protection for their scientific research and to license those patents to the private sector. This statute has been hailed as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century" because it "unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance." *Innovation's Golden Goose*, THE ECONOMIST'S TECHNOLOGY QUARTERLY (Dec. 2002).

Among the more prominent technological advances made available to the public through Bayh-Dole licensing are the Google and Lycos Internet search engines (Stanford and Carnegie Mellon Universities, respectively); the co-transformation process, a pioneering recombinant DNA technology used to make pharmaceutical products that treat many different diseases and ailments (Columbia University); the cancer drug Taxol (Florida State University); and the nicotine patch (UCLA). *See* Mary Margaret Styer, et al., *A Guide Through the Labyrinth: Evaluating and Negotiating a*

---

[1] The parties' letters of consent to the filing of amici briefs have been lodged with the Clerk. Pursuant to Rule 37.6, amici state that no counsel for a party has written this brief in whole or in part and that no person or entity, other than amici, their members, or their counsel, has made a monetary contribution to the preparation or submission of this brief.

[2] A full list of amici filing this brief is set out in Appendix A.

University Technology Transfer Deal, 11 B.U. J. SCI. & TECH. L. 221, 222-23 (2005); *Technology Transfer Stories: 25 Innovations that Changed the World*, (2006 ed.) (available at http://www.autm.net/documents/AUTM_BWR.pdf).

Universities use royalty revenue from their licenses to fund further scientific research and educational programs. The continued success of the important national policy embodied in the Bayh-Dole Act depends on the stability of patent licenses, which would be threatened if MedImmune's position were accepted in the present case. In particular, MedImmune's arguments urge an unwarranted expansion of the holding in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969) that would erode the sanctity of contracts and interfere with vital policies favoring amicable resolution of commercial matters.

Amici The Trustees of Columbia University in the City of New York ("Columbia"), and The Board of Trustees of the Leland Stanford Junior University ("Stanford") have an additional, unique interest in the outcome of this case. They are respondents in *MedImmune, Inc. v. Centocor, Inc., et al.*, No. 05-656, *pet. for cert. filed* Nov. 22, 2005. MedImmune's declaratory judgment action in the *Centocor* litigation was dismissed on the same jurisdictional basis as its complaint in this case; moreover, MedImmune's petition for certiorari in *Centocor* presents the same question as this case. Because MedImmune's actions in *Centocor* strongly highlight the issues underlying the *Genentech* case, Columbia and Stanford are well suited to address the pernicious ramifications of the legal standard MedImmune advocates.

INTRODUCTION AND STATEMENT OF THE CASE

The Federal Circuit decided *Genentech* on October 18, 2005, subsequent to, and in reliance upon, its decision in

MedImmune v. Centocor, 409 F.3d 1376 (Fed. Cir. 2005). MedImmune, however, reversed that chronological order, filing its petition for certiorari in *Genentech* on November 10, 2005, and later petitioning for certiorari in *Centocor* (Nov. 22, 2005). As a result, *Genentech* is before this Court on the merits and the petition in *Centocor* is being held. Despite similar procedural and jurisdictional histories, the facts of the two cases differ. Accordingly, a brief recitation of MedImmune's conduct in *Centocor* should inform any analysis of the practical consequences of the tactics MedImmune asks this Court to condone.

In late 1998, MedImmune approached Columbia seeking a license for U.S. Patent No. 5,807,715 (the '715 patent), which Columbia jointly owns with Stanford. The '715 patent reflects the ground-breaking work of prominent research scientists in the field of monoclonal antibody technology. Columbia referred MedImmune to Centocor, Inc., the exclusive licensee of the '715 patent. Thereafter, MedImmune spent nearly two years negotiating a sublicense with Centocor. During that process, MedImmune analyzed and obtained opinions from multiple law firms about the validity of the patent and whether it covered MedImmune's product Synagis®. MedImmune's negotiating posture included a number of arguments (*e.g.*, patent invalidity and non-infringement) designed to drive down the negotiated royalty rate. Although the universities disagreed with MedImmune's contentions, important concessions were made in order to reach an accord satisfactory to all parties. Ultimately, the sublicense agreement was approved at a reduced royalty rate – less than originally proposed and less than if MedImmune's various contentions had already been rejected in court – and a substantial postponement in the date on which MedImmune's obligation to pay royalties began. *See* 271 F. Supp. 2d 762, 765 (D. Md. 2003).

After signing the sublicense agreement in December 2000, MedImmune began making royalty payments under the '715 patent as of the date specified in the contract. Having resolved all issues with MedImmune, the universities ordered their affairs around the agreed-upon royalty payments, relying on expected revenues to fund further scientific research and educational activities. Unbeknownst to them, however, MedImmune was plotting a very different course. Within days of executing the sublicense agreement, MedImmune sent a copy to its current litigation counsel and began assessing options for a lawsuit. Some fifteen months later, MedImmune first contacted Centocor requesting consent to the cessation of royalties. MedImmune did not identify any meaningful change of circumstances that occurred after it signed the sublicense agreement or any ambiguity in the agreement. Unable to secure Centocor's assent in its newly-proposed non-payment option, and explicitly indicating that it would continue to make the royalty payments specified in the agreement, MedImmune filed a declaratory judgment suit asserting the same invalidity and non-infringement arguments it had raised during the original pre-sublicense negotiations. *See* 409 F.3d at 1378; 271 F. Supp. 2d at 765.

Prior to the Federal Circuit's decision in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *cert. dismissed*, 543 U.S. 941 (2004), Columbia and Stanford filed a motion to dismiss MedImmune's complaint for lack of jurisdiction. Although the motion was initially denied, the district court eventually dismissed the case after *Gen-Probe* was decided. The district court held that where there was a license agreement with which all parties were complying – and expressing their continuing intention to comply – there was no actual controversy under 28 U.S.C. § 2201(a). 2004 U.S. Dist. LEXIS 28800, at **8-9 (D. Md. June 17, 2004).

In affirming, the court of appeals applied its holding in *Gen-Probe* and explained why MedImmune was incorrect in asserting that *Gen-Probe* was inconsistent with Supreme Court and Federal Circuit authority. 409 F.3d at 1379-82. Moreover, the court held that MedImmune "can have no apprehension of suit at all" since "there is nothing for which Centocor can sue MedImmune." *Id.* at 1381. This conclusion follows ineluctably from the fact that "[i]t is undisputed that MedImmune continues to pay timely royalties for Synagis® and is not otherwise in breach of the agreement." *Id.* As the court explained, "a license is, by its nature, an agreement not to litigate. A licensor agrees to receive royalties or other consideration from the licensee in exchange for a covenant not to sue or disturb the licensee's activities." *Id.* at 1379 n.1.

The circumstances of the *Centocor* litigation highlight the more pernicious aspects of the tactics employed by licensees. The licensee in *Centocor* (MedImmune) made the initial approach to the patent owner requesting a license; the licensee sought the license under a patent that had already issued; the parties negotiated and had every opportunity to explore all aspects of their differing views on patent validity and infringement; the parties reached a written accord reflecting a compromise that settled all outstanding issues; there are no changed circumstances subsequent to execution of the agreement; and the licensee continues to enjoy all the benefits of the agreement and, in return, continues to make all royalty payments; the parties remain bound by the contract to which they are adhering.

This brief recitation provides some context for the following arguments against the disruption of established legal relationships that will occur if this Court reverses the judgment and adopts the standard MedImmune urges. These untoward consequences are not merely hypothetical, nor are

they a rhetorical parade of conjured-up horribles. They are the actual circumstances in which Stanford and Columbia were placed by MedImmune's tactics. As a practical matter, they are the inequitable reality any patent holder may face if MedImmune's position is upheld.

SUMMARY OF ARGUMENT

1. Article III precludes jurisdiction over issues resolved in an ongoing license agreement that all parties continue to honor. Indeed, the licensee here positively insists on maintaining the agreement in force to keep all the benefits for which it bargained. The circumstance of a voluntary, still-operational agreement, with the plaintiff demanding retention of its negotiated shelter, readily distinguishes this case from the two principal authorities being invoked to support Article III jurisdiction: *Altvater v. Freeman*, 319 U.S. 359 (1943), and *Steffel v. Thompson*, 415 U.S. 452 (1974). This circumstance also defeats the licensee's ability to meet several established Article III requirements.

At the core of its argument, MedImmune urges an extension of *Lear* to entitle a licensee, asymmetrically, to press its challenges while retaining the benefits of its license without the risks faced by an infringer. But *Lear* merely protected a licensee who faced actual litigation commenced by the licensor; it did so by permitting a full range of defenses, including the defense of patent invalidity. MedImmune seeks to transform that limited protection into an offensive weapon for licensees to wield against licensors at any time. *Lear* does not compel that result; nor does the rationale of *Lear* support it. Just as the Court has previously refused to extend *Lear*, it should do so again now.

In fact, even if the express policy underpinning of *Lear* – promoting prompt adjudication of patent validity – is

viewed (incorrectly) as the only policy relevant to the question, that policy itself is contrary to MedImmune's contention. MedImmune's argument would permit a prospective licensee to forgo all pre-agreement opportunities to litigate patent validity, to enter into a negotiated resolution of all outstanding issues (including patent validity), and to wait years before launching litigation against a patent holder who made substantial concessions in the original agreement and has no recourse against the belatedly litigious licensee.

2. The rule MedImmune advocates assumes that in the circumstances presented in this case, federal patent law displaces valid contracts that are fully enforceable under state law. MedImmune's contention is wrong as a matter of federalism and general patent law, and especially so in the context of universities fulfilling the statutory mission of the Bayh-Dole Act. The invaluable benefits that the Act has achieved (encouraging inventions by university researchers to benefit the public) would be drastically curtailed if licensors lose the repose that their contractual agreements were intended to produce. Under MedImmune's approach, substantial litigation expenses would have to be built into the royalty calculations of license agreements, thus raising the cost of providing breakthrough technology to the public.

3. Even if Article III requirements could be satisfied by a plaintiff in MedImmune's position, a declaratory judgment action should not be allowed to proceed. The standard employed by the Federal Circuit in cases where license agreements remain operational, is an appropriate guideline for district courts asked to entertain claims under the Declaratory Judgment Act. Indeed, the line drawn by the Federal Circuit is consistent with this Court's precedents, with the need to consider the public interest, and with the practical exigencies of the world of commerce.

ARGUMENT

I. A LICENSEE'S CONTINUING, VOLUNTARY PERFORMANCE OF ITS AGREEMENT TO PAY PATENT ROYALTIES BARS ARTICLE III JURISDICTION OVER THE LICENSEE'S DECLARATORY JUDGMENT CHALLENGE TO THE PATENT'S VALIDITY, ENFORCEABILITY, OR COVERAGE

A. Traditional Article III Standards Preclude Jurisdiction

"'[N]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.'" *DaimlerChrysler Corp. v. Cuno*, 126 S. Ct. 1854, 1861 (2006) (quotation omitted). This principle "is as true of declaratory judgments as any other field." *United Pub. Workers v. Mitchell*, 330 U.S. 75, 89 (1947); *accord U.S. Nat'l Bank of Oregon v. Indep. Ins. Agents of Am.*, 508 U.S. 439, 446 (1993).

The Court has elaborated the constitutional requirements through a number of overlapping doctrines. *See Allen v. Wright*, 468 U.S. 737, 750 (1984). Because of that overlap, there are multiple doctrinal ways of identifying the fundamental problem presented by suits filed by licensees who continue to perform under operational agreements: plaintiff voluntarily entered into an agreement that affords substantial benefits that it positively insists on retaining even while it litigates. This amicus brief does not exhaustively explore all the ways in which this core fact defeats Article III jurisdiction. Instead, this brief explains why a selected few of the established Article III requirements cannot be met by a

licensee like MedImmune while it enjoys the self-protection afforded by the license agreement.

At the outset, it is clear that neither of the two principal authorities invoked to support Article III jurisdiction involves the distinctive feature of the present case – plaintiff's continuing, voluntary performance of an operative agreement it seeks to maintain. Neither *Altvater* nor *Steffel* involved an unquestionably valid agreement which both parties were performing without breach. In *Altvater*, there was no license. The agreement had already been terminated, the patentee had sued for infringement and other claims, and the licensee's continuing payment of royalties was wholly *involuntary*, "under the compulsion of an injunction decree." 319 U.S. at 365. In *Steffel*, there was plainly no agreement by the plaintiff not to distribute protest handbills on private property. He ceased the protest activities under "a genuine threat of enforcement" of a state criminal trespass statute. 415 U.S. at 475. The parties also stipulated that if plaintiff engaged in such conduct "a warrant would be sworn out" and he would be arrested. *Id.* at 456 & n.4. By no stretch of the imagination is MedImmune's voluntary performance of its agreement comparable to compliance with a coercive injunction (*Altvater*) or forbearance under a genuine threat of criminal prosecution (*Steffel*).

For Article III jurisdiction to exist, plaintiff must show: a legally cognizable "injury in fact" (1) that is "concrete and particularized," (2) that is "fairly traceable" to the defendant's action, and (3) that can be redressed by a favorable judicial decision. *McConnell v. FEC*, 540 U.S. 93, 225-27 (2003); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Allen*, 468 U.S. at 751-52, 755-59. A plaintiff must "show that there is a substantial controversy, between parties having adverse legal interests, *of sufficient immediacy and reality* to warrant the issuance of a

declaratory judgment." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *Whitmore v. Arkansas*, 495 U.S. 149, 155, 158 (1990); *City of Los Angeles v. Lyons*, 461 U.S. 95, 101 (1983). In various ways, suits like MedImmune's fall short under these standards.

The situation presented by MedImmune's agreement with the respondents – and even more starkly by its agreement with Centocor – is a common one, replicated in the daily routine of patent licensing that spreads technology throughout the economy. A patentee and a firm wanting to engage in conduct arguably covered by a patent enter into an extended negotiation about whether the conduct is covered and whether the patent is a valid, enforceable one. In that negotiation, they press their respective views and also consider the costs (*e.g.*, in money, delay, distraction of personnel) of litigating the dispute to a judicial resolution. Often, they including a desire to avoid the costs of litigation, they reach an agreement in which the amount paid reflects assessments of likely litigation outcomes: more than if the licensee were to prevail in court; less than if the patentee were to prevail in court. The licensee gets substantial benefits: the right to practice the patent free of litigation threat; the freedom to do so immediately without awaiting years of litigation; and a negotiated royalty rate reduced from the patentee's initial offer to reflect any perceived uncertainty over issues of patent validity, enforceability, and coverage. Indeed, the very point of the agreement is to settle the dispute and to put the technology into practice without wasteful expenditures on judicial processes.

The post-agreement state of repose is inherent in the parties' arrangement and derives from the options facing potential licensees: "to use the rights under a license, to not use the rights (and avoid any need for a license), or to use the rights without a license and litigate any infringement claim."

John W. Schlicher, LICENSING INTELLECTUAL PROPERTY: LEGAL, BUSINESS, AND MARKET DYNAMICS 48 (1996). Once the prospective licensees opt to execute negotiated agreements, their licenses "are often best viewed as settlements of potential future litigation." *Id.* at 49.

There is a fatal tension between the Article III requirements of a live controversy of sufficient immediacy and reality (injury-in-fact, traceability, redressability) and the absence of any potential liability for infringement during the full term of a license agreement as the licensee enjoys immunity from any such claim. *See De Forest Radio Tel. Co. v. United States*, 273 U.S. 236, 241 (1927). Licensees who make timely payments under their agreements not only lack any present threat of an infringement claim, but also enjoy a binding contractual promise barring precisely that claim. *See* Kim R. Smith, *Foreclosure of License Validity Challenges with Procedural Barriers*, 61 J. PAT. OFF. SOC'Y 690, 701 (1979); Note, *Patent Licensee Standing and the Declaratory Judgment Act*, 83 COLUM. L. REV. 186, 197 (1983). Moreover, if the licensee stops performing under the agreement and is sued for breach, there is no impediment to the defense of patent invalidity. *Lear*, 395 U.S. 653. Should another party successfully challenge the patent's validity, the royalty obligation would cease. *Id.* And, if the licensee learns of any reason to doubt the patent's validity because of prior art it can commence a re-examination proceeding at the Patent and Trademark Office ("P.T.O.") while still honoring its obligation to pay royalties. 35 U.S.C. §§ 301-307.

The lack of Article III jurisdiction in this case fits within several well-established jurisdictional categories. For example, the licensee is fairly viewed as failing to meet the threshold requirement of legally cognizable injury. When a party has made an exchange for equal value, it has not suffered a harm. *See Dura Pharms., Inc. v. Broudo*, 544 U.S.

336, 342 (2005) ("as a matter of pure logic, at the moment the transaction takes place, the plaintiff has suffered no loss; the inflated purchase payment is offset by ownership of a share that at that instant possesses equivalent value"). When a licensee like MedImmune enters into its license agreement, it receives what it has judged to be equal value in return for its payment: freedom from suit and from the risk of an injunction against its business and from a much higher royalty rate should any uncertainties about the validity, enforceability and coverage be resolved in favor of the patentee. As long as the licensee retains those benefits, it keeps the agreed-upon equivalent of the payment obligation about which it seeks to complain. Of course, repudiation would eliminate that equal value, as in *Lear*. But without repudiation, the licensee suffers no cognizable harm.

MedImmune's argument also may be viewed as foundering on the causation requirement of an injury traceable to the defendant's action. Its claimed injury – payment of royalties for practicing the patents – was a voluntary obligation undertaken in light of the usual business and legal uncertainties. That act, like the act of a third party, breaks the chain of causation leading back to the licensor. Distinctions of this sort are commonplace in causation analysis and echo the distinction that, in a different context, informed the plurality opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525-26 (1992) (Stevens, J.) (noting difference between express warranty claims imposed under State law and those imposed "*by the warrantor*").

MedImmune's claim can also be seen as failing the Article III justiciability standard in another critical respect. The interest MedImmune asserts – cessation of agreed upon payments – is entirely dependent on the lawsuit. After all, the obligation arose from MedImmune's voluntary agreement, and would end (during the prescribed term of the

license) only as a result of the litigation. But this Court has held that "an interest that is merely a 'byproduct' of the suit itself cannot give rise to a cognizable injury in fact for Article III standing purposes." *Vermont Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 773 (2000). That principle is fully applicable here, where MedImmune's alleged injury is necessarily framed in terms of the result in the lawsuit.

Finally, these circumstances also fit within another established category in which Article III jurisdiction is lacking. This Court has made clear that a valid state law bar to the relief sought – an "adequate and independent state ground" – eliminates Article III jurisdiction to hear a federal-law claim. *See Coleman v. Thompson*, 501 U.S. 722 (1991); *Ake v. Oklahoma*, 470 U.S. 68, 75 (1985); *Herb v. Pitcairn*, 324 U.S. 117, 126 (1945); *Enter. Irrigation Dist. v. Farmers Mut. Canal Co.*, 243 U.S. 157, 164 (1917). Although stated in terms of this Court's review of state court judgments, the principle is not in any way dependent on the language of 28 U.S.C. § 1257. The operative principle is that there is no case or controversy if state law validly bars relief sought in federal court. One kind of state ground that can be adequate and independent is a waiver or other forfeiture, such as a procedural default. *See Louisville & Nashville R.R. v. Woodford*, 234 U.S. 47, 51 (1914); Richard H. Fallon Jr., et al., HART AND WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 525 n.2 (4th ed. 1996) ("[t]he same principle operates when there is an antecedent state law *procedural* ground – ordinarily that the party seeking Supreme Court review failed to raise the federal question in accordance with state procedural rules").

Similarly, in this case (and in *Centocor*) MedImmune does not suggest that its agreements are invalid in any way. The sole basis, therefore, on which MedImmune seeks to

cease paying royalties is by federal preemption of contracts whose validity and enforceability are unquestioned under state law. Under this analytical framework, therefore, the ultimate jurisdictional issue turns on the preemption question. From that perspective, it should be clear that MedImmune's position cannot prevail, especially where it is *relying* on the same license as enforceable under state law – paying royalties and obtaining all the benefits for which it bargained (including the right to use the patented invention, immunity from a claim of infringement, treble damages and attorneys' fees; and, in return, all the favorable consequences of being the first to market).

B. Federal Law Respects the Licensor's Repose While the Licensee is Sheltered by the License

A contract creates repose that should preclude federal jurisdiction as long as no party is threatening to terminate the agreement. At the core of the argument of MedImmune and its amici is the submission that federal patent policy upsets, rather than respects, this repose by allowing a challenge to the patent's validity, enforceability, or coverage, even while the licensee maintains the benefits of the license. This Court should reject that submission. A licensee who chooses to maintain the shelter of the license has no standing to contest the repose that is the essence of the agreement.

1. *Lear* Does Not Authorize a Challenge to Patent Validity in These Circumstances

The principal basis upon which MedImmune argues that federal patent law should control rests on *Lear*. Much of MedImmune's argument, however, is premised on a misreading of *Lear*, coupled with a misguided effort to expand *Lear* well beyond its limited scope. Before *Lear*,

licensors had considerable power over their licensees, including the doctrine of licensee estoppel that precluded a licensee from challenging the validity of the license – even to defend a breach of contract suit by the patentee. *Lear* abolished the licensee estoppel doctrine to provide patent licensees with a full range of defenses and established a particular measure of parity between the legal arsenals of licensees and patent holders. *See* 395 U.S. at 657.

MedImmune now wishes to transmogrify the protection afforded by *Lear* into an equilibrium-destroying weapon to give licensees an unfettered right to challenge a patent even as they continue to enjoy the contractual right to practice that patent and retain the other benefits of the license. *Lear* never contemplated such a situation. *See, e.g.*, William C. Rooklidge, *Licensee Validity Challenges and the Obligation to Pay Accrued Royalties:* Lear v. Adkins *Revisited (Part II)*, 69 J. PAT. & TRADEMARK OFF. SOC'Y 5, 10 (1987) ("If the licensee filed a declaratory judgment action without repudiation, there should be no jurisdiction because of a lack of 'a case or controversy.' The Supreme Court in *Lear* did not write that requirement out of the Declaratory Judgment Act"). Indeed, as pointed out in Justice White's concurrence, the *Lear* licensee "concede[d] that it would be estopped to contest the validity of any patent issued to Adkins . . . so long as it continued to operate under that agreement." 395 U.S. at 679 n.1 (quoting *Adkins v. Lear, Inc.*, 52 Cal. Rptr. 795, 805 (Cal. App. 1996)).

The licensee in *Lear* stopped paying royalties three years prior to the commencement of suit by the patentee. *See* 395 U.S. at 661-62. Hence, unlike the instant case, "a controversy existed in the *Lear* case." Note, *Patent Licensee Standing*, 83 COLUM. L. REV. at 200. All *Lear* held was that a licensee could raise a defense of patent invalidity when sued in state court by a patentee for royalties due. *See id.* at

200-01. MedImmune and its amici incorrectly equate the absence of estoppel (*Lear*), with the presence of a justiciable controversy. *Lear*, which did not involve any Article III issue, neither requires nor even supports that conclusion.

Aside from the dispositive factual differences between this case and *Lear*, there are additional reasons why *Lear* should not be extended to reach the facts presented here. *Lear*, decided the same Term as *Fortner I*, has been described as the apex of an "anti-patent anti-monopoly" milieu. Rooklidge, *Licensee Validity Challenges* 69 J. PAT. & TRADEMARK OFF. SOC'Y 5 at 15 & n.22; Rochelle Cooper Dreyfuss, *Dethroning* Lear: *Licensee Estoppel and the Incentive to Innovate*, 72 VA. L. REV. 677, 724 (1986). In the intervening four decades, the Court has employed more discerning analyses in both areas of law. *See, e.g., Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 126 S. Ct. 1281, 1289-92 (2006). That is good reason not to extend *Lear*.

Indeed, the Court has already declined to extend *Lear*. In *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257 (1979), the Court held that federal patent law does not preempt the enforcement of a contract valid under state law. Although *Aronson*'s facts differ from those here, the Court's opinion is instructive. The parties entered into a licensing agreement while a patent application was pending, specifying that the royalty rate would drop if the patent application was not allowed within five years. When the patent did not issue by the prescribed time (it was subsequently rejected by the Patent and Trademark Office), the licensee continued to pay royalties at the reduced rate for 14 years. By then, rivals with no obligation to pay royalties had entered the market and the licensee refused to make further payments. *See Quick Point Pencil Co. v. Aronson*, 425 F. Supp. 600, 601 (E.D. Mo. 1976). The licensee subsequently sued for a declaratory judgment, claiming that "state law which might otherwise

make the contract enforceable, was pre-empted by federal patent law." 440 U.S. at 260. Relying on *Kewanee Oil* and *Brulotte v. Thys Co.*, the Court rejected the licensee's claim, holding that "[s]tate law is not displaced merely because the contract relates to intellectual property which may or may not be patentable." *Id.* at 262. The Court noted that the parties had contracted with "full awareness of . . . the possibility that a patent might not issue." *Id.* at 261. Of even additional importance for present purposes, *Aronson* concluded that "neither the holding nor the rationale of *Lear*" controlled in those circumstances. *Id.* at 264. Forgoing an opportunity to extend *Lear*, the Court recognized that there were valid economic reasons why a firm would be willing to "pay for the opportunity to be first in the market" even in the absence of a valid patent or trade secret, and that "[f]ederal patent law is not a barrier to such a contract." *Id.* at 266.

Today, and in the circumstances presented by MedImmune, there is even less justification to extend *Lear*. First, even at the time of *Lear*, the value of clearing away bad patents was dominant (over policies favoring licensing, litigation avoidance, and respect for contracts) only where litigation was already underway and the contract was no longer being respected. There is no reason to apply *Lear*'s balance when the licensee insists on continued operation of the contract. More generally, since *Lear* this Court has taken a less one-sided view of the multiple policies underlying federal law affecting intellectual property, as reflected in *Kewanee Oil*, *Aronson* and *Illinois Tool*. *See also AirLine Pilots Ass'n, Int'l v. O'Neill*, 499 U.S. 65, 78 (1991) (policy favoring contractual resolution of labor disputes).

Even as to the policy that *Lear* emphasized, the statutory law has been changed in a vital respect. Amendments subsequent to *Lear* provide that any party may request a re-examination by the P.T.O. 35 U.S.C. §§ 301-

307. Accordingly, *Lear*'s concern for resolution of patent validity issues would not be thwarted if this Court affirms the judgment in this case.

Further, to the substantial extent that *Lear* was expressly premised on a policy of promoting prompt adjudication of patent validity (395 U.S. at 673-74), that policy is not advanced in the slightest by conferring on licensees an open-ended opportunity to challenge patent validity at any time during the term of the license agreement. *See, e.g., Centocor*, 409 F.3d at 1377-78 (MedImmune waited sixteen months after license before suing); *cf. Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1373 (6th Cir. 1976) (Markey, C.J., sitting by designation) ("Whatever boon *Lear* may have provided those who take licenses under certain conditions, it cannot be interpreted so broadly as to condone a kind of gamesmanship, wherein an alleged infringer, after employing the judicial system for months of discovery, negotiation, and sparring, abandons its challenge to validity, executes a license in settlement, and then repudiates the license and seeks to start the fight all over again in the courts"). To the contrary, it is far more consistent with the policy articulated in *Lear* to respect operative licenses by barring the licensee's suit. Doing so encourages potential licensees to seek judicial resolution of validity issues *before* entering a license agreement. *See* Dreyfuss, *Dethroning* Lear, 72 VA. L. REV. at 722 ("[T]he right to challenge validity, standing alone, will not stimulate early patent challenges. Rather, that incentive is better furnished by a rule that warns licensees that if they do not challenge at first opportunity, they may lose that right forever"); Schlicher, *A Lear v. Adkins Allegory*, 68 J. PAT & TRADEMARK OFF. SOC'Y 427 (1986).

2. Federal Patent Law Should Respect, Not Preempt, License Agreements Like MedImmune's

There are also compelling affirmative reasons why, in the circumstances presented here, federal patent law should not preempt operative contracts. First, as a matter of federalism, there is a general presumption against preemption, and intellectual property cases reflect this principle. *See, e.g., Brulotte, Kewanee, Aronson.* Second, the presumption is fortified here by the patent statute's long-accepted protection of a patentee's broad freedom to parcel out its exclusivity rights as it chooses (subject to very limited constraints). *See, e.g., Zenith Radio Corp. v. Hazeltine*, 395 U.S. 100, 135-36 (1969); *Cont'l Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 423-25 (1908); *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 88-91 (1902).

Preemption in these circumstances would adversely affect patent licensing, which fosters competition and economic growth and efficiency by making technology and intellectual property more widely available. *See* Note, *Patent Licensee Standing*, 83 COLUM. L. REV. at 206 ("[i]f current licensees are allowed to bring offensive patent validity challenges, the patent system may be injured. Injury to the patent system may, in turn, harm our long-standing policy of promoting invention, and may ultimately reduce both competition and technological advance"); 7 PAT. L. PERSP. § 12.4[6] (Matthew Bender 2d ed. 2005) at 12-123 ("[W]e may see a major contraction in the number of licenses granted"). Indeed, unrestricted licensee suits would burden patentees whose "constitutionally recognized property right may become too expensive to maintain" and would "ultimately result in higher costs as patentees increase their fees to cover anticipated litigation expenses." *See* Note, *Patent Licensee Standing*, 83 COLUM. L. REV. at 192, 211. These costs will

undoubtedly be passed along to the public, "thus diminishing the benefits the public currently receives from the patent system." *Id.*; *see also* Emmette F. Hale, III, *The "Arising Under" Jurisdiction of the Federal Circuit: An Opportunity for Uniformity in Patent Law*, 14 FLA. ST. U. L. REV. 229, 259 (1986) (making same point). Many useful technologies are licensed by universities for relatively small financial returns; the prospect of expensive patent litigation would at a minimum raise the cost of making these inventions available to the public.

Alternatively, prospective licensors would seek to ensure the benefit of their bargain by filing an infringement suit first and then entering into a license agreement as part of a consent decree. *See* 7 PAT. L. PERSP. § 12.4[6] at 12-124. Licensors would thereby obtain the benefit of *res judicata* with respect to the licensees' patent validity claims. *See Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 476-77 (Fed. Cir. 1991); *Buckley v. Airshield Corp.*, 977 F. Supp. 375, 377-78 (D. Md. 1997). Encouraging licensors to file such plainly unnecessary suits whenever they consider granting a license would be detrimental in obvious ways to the judicial system, the patent system, and the flow of commerce.

3. The Policy Considerations are Reinforced in the University Setting By the Bayh-Dole Act

The adverse consequences of MedImmune's arguments in this case would be particularly damaging to educational institutions that support scientific innovation in the United States by reinvesting royalty payments in further research and educational activities. *Cf. eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1840 (2006) (noting that most university researchers prefer to license their patents rather than obtain financing to market inventions

themselves). As universities, public and private, divert funds from research and educational programs to combat the licensee gamesmanship MedImmune urges, the licensees face no commensurate risk. That result is plainly contrary to the public interest (especially when taxpayer money is being diverted from research) and, more specifically, to the important national policy embodied in the Bayh-Dole Act.

That Act is designed to promote the transfer of useful (and often ground-breaking) technology from non-profit research institutions to the public. As Congress understood, special circumstances characterize the reality of patent licensing by universities. First, universities lack the internal capacity to bring their inventions to market. They are not commercial institutions; they have no manufacturing capability; and their financial resources are dedicated to educational and research purposes. As a consequence, all prospects for commercial application of the patents must come from the licensee; this reality gives the prospective licensee greater leverage than it would enjoy in negotiations with a commercial patentee.

Second, many universities do not have sufficient litigation budgets to spend the millions necessary to defend their patents. The need for true patent peace with licensees is therefore particularly compelling in this context, a point that is underscored by the significant technology transfers from institutions with relatively modest endowments and financial resources. Major advances in genetic research flowed from inventions licensed by Tufts University (Bead Away technology that helps analyze genetic variation and function) and the University of Maryland, Baltimore County (Cell station reactor that speeds the discovery and process development stages of fermentation and culture-based medical products). Researchers at North Dakota State University invented an additive for weed control that reduces

farmer's costs by half. New technology developed at the University of Akron eases eye strain from viewing computer monitors and other consumer products. Under the regime MedImmune posits, costs would skyrocket for providing the public with the benefit of these and hundreds of other inventions in fields such as agriculture, biotechnology, computer science, health, medicine, safety, nanotechnology and the environment. *See generally Technology Transfer Works: 100 Cases from Research to Realization* (2006) http://www.autm.net/documents/06ReportsFromField.pdf. Because the Bayh-Dole Act expresses so clear a mandate to promote the efficient transfer of technology for public benefit, it reinforces the view that, at least in the university setting, no expansive preemption implications can be drawn from the Patent Act.

When the practical realities of the licensing arrangement are properly understood, it is evident that Article III would not permit a lawsuit commenced by a party adhering to a binding resolution of the very issue it seeks to litigate. For just this reason, the line drawn by the Federal Circuit comports with established Article III jurisprudence because it accurately reflects the fact that at the crucial time (*i.e.*, the date a complaint is filed), the licensee is fully protected by the agreement it voluntarily entered and continues to honor. Whether viewed under the rubric of standing, injury, traceability or causation, a licensee in good standing therefore falls outside the ambit of Article III.

II. EVEN IF MEDIMMUNE'S SUIT PRESENTED A CASE OR CONTROVERSY, IT SEEKS EQUITABLE RELIEF THAT SHOULD BE CATEGORICALLY UNAVAILABLE UNDER THE DECLARATORY JUDGMENT ACT

The absence of a live case or controversy should bring the analysis to a close with the Federal Circuit's standard upheld. Surely that should be the case when, as in *Centocor*, the patent issued prior to the license, the licensee had ample opportunity to review and assess the patent (and did so, with multiple opinions of counsel), and the licensee obtained substantial concessions on timing and amount of royalty payments during negotiations that culminated in the resolution set forth in the license agreement.

This Court has long recognized that the Declaratory Judgment Act "was an authorization, not a command. It gave the federal courts competence to make a declaration of rights; it did not impose a duty to do so." *Public Affairs Assocs., Inc. v. Rickover*, 369 U.S. 111, 112 (1962). Thus, in assessing a declaratory judgment claim, "[i]t is always the duty of a court of equity to strike a proper balance between the needs of the plaintiff and the consequences of giving the desired relief." *Eccles v. Peoples Bank of Lakewood Village*, 333 U.S. 426, 431-32 (1948). Recognizing that the Act "created an opportunity, rather than a duty, to grant a new form of relief to qualifying litigants" (*Wilton v. Seven Falls Co.*, 515 U.S. 277, 288 (1995)), the Court has expressly endorsed the views of Professor Edwin Borchard, the acknowledged author of the Act (*id.*):

> We agree, for all practical purposes, with Professor Borchard, who observed half a century ago that "there is . . . nothing automatic or obligatory about the assumption of 'jurisdiction' by a federal court"

to hear a declaratory judgment action. Borchard, DECLARATORY JUDGMENTS, at 313.

Inherent in the grant of discretionary authority to issue declaratory relief is the companion authority for appellate courts to set appropriate boundaries for the exercise of that discretion. In the absence of limits and standards, discretion would devolve into random, even arbitrary, decisions that would diminish the public's ability to assess precedent as a guide to conduct. Any semblance of predictability, or instruction for ordering one's affairs, would be lost. But, this Court has stoutly resisted the notion that discretion should drift into a regime of random decisionmaking. Where a trial court exercises discretion, its "judgment is to be guided by sound legal principles" because "[d]iscretion is not whim, and limiting discretion according to legal standards helps promote the basic principle of justice that like cases should be decided alike." *Martin v. Franklin Capital Corp.*, 126 S. Ct. 704, 710 (2005) (quoting *United States v. Burr*, 25 F. Cas. 30, 35 (C.C. D. Va. 1807) (Marshall, C.J.)); *cf.* Henry J. Friendly, *Indiscretion About Discretion*, 31 EMORY L.J. 747, 771-73 (1982). Lower courts' discretion is necessarily constrained by accumulated precedent, by guidelines established in appellate decisions, and by the mandate that courts "must also take account of the public interest." *U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 26 (1994). Assessment of the public interest results in the articulation of general rules that govern the lower courts, a course this Court follows in multiple contexts. *E.g.*, *Martin*, 126 S. Ct. at 710; *Wilton v. Seven Falls Co.*, 515 U.S. 277, 288 (1995); *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 416, 422 (1975).[3]

---

[3] *See also Local 28 of the Sheet Metal Workers' Int'l Assoc. v. EEOC*, 478 U.S. 421, 475 (1986) ("While the fashioning of 'appropriate'

In the operative-license context, the Federal Circuit standard articulated in *Gen-Probe*, *Centocor*, and *Genentech* is the most appropriate one for the exigencies of patent licensing. The standard serves Article III principles, general principles governing the availability of judicial relief, and the policies specific to the patent context. *See* pages 8-20 *supra*.

The Federal Circuit standard is directly rooted in Article III tenets (even if, as this portion of the brief assumes, Article III does not of its own force *require* this standard). *See* pages 8-14 *supra*; *see also Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298-99 (1979) (Article III requires plaintiff to show "credible" threat of prosecution before challenging statute); *Younger v. Harris*, 401 U.S. 37, 42 (1971) ("persons having no fears of state prosecution except those that are imaginary or speculative, are not to be accepted as appropriate plaintiffs"); *Golden v. Zwickler*, 394 U.S. 103, 109-10 (1969) (plaintiff must show that threat of prosecution is real and immediate before challenging validity

---

remedies for a particular Title VII violation invokes the 'equitable discretion of the district courts,' we emphasize that a court's judgment should be guided by sound legal principles. In particular, the court should exercise its discretion with an eye towards Congress' concern that race-conscious affirmative measures not be invoked simply to create a racially balanced work force.") (quotation omitted); *Ford Motor Co. v. EEOC*, 458 U.S. 219, 227 (1982) ("[W]hen Congress invokes the Chancellor's conscience to further transcendent legislative purposes, *what is required is the principled application of standards consistent with those purposes* and not equity [which] varies like the Chancellor's foot.") (emphasis added; quotation omitted); *United States v. Criden*, 648 F.2d 814, 818 (3d Cir. 1981) ("[T]he contours of a guiding rule or even principle may develop as the courts begin to identify the policies which should control. Thus, for example, although the selection of an appropriate remedy has been generally deemed to lie in the equitable discretion of the trial judge, *after experience has accumulated the appellate courts may decide that a specific remedy should be awarded as a general rule*") (emphasis added).

of statute). Even if, *arguendo*, Congress could press the limits of Article III and constitutionally provide for declaratory judgment suits in circumstances like this, the Federal Circuit bar on such suits is a proper standard limiting the exercise of equitable authority under the Declaratory Judgment Act at least until Congress speaks to the contrary.

A rule denying relief in the present circumstances also reflects the broadly applicable principle that a claimant's voluntary act may operate to disentitle him to relief. *See U.S. Bancorp*, 513 U.S. at 25 ("'a suitor's conduct in relation to the matter at hand may disentitle him to the relief he seeks'") (quoting *Sanders v. United States*, 373 U.S. 1, 17 (1963) and citing *Fay v. Noia*, 372 U.S. 391, 438 (1963)). The Court recently applied this principle in the context of appellate jurisdiction. *Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc.*, 126 S. Ct. 980, 988 (2006), held that a court of appeals is "powerless" to grant relief a party chose to forgo in the district court. The analysis in *Unitherm* was informed by the statement in *Yakus v. United States*, 321 U.S. 414, 444 (1944), that "[n]o procedural principle is more familiar to this Court than that a . . . right may be forfeited . . . by the failure to make timely assertion of the right before a tribunal having jurisdiction to determine it." (*quoted in Unitherm*, 126 S. Ct. at 988). A prospective licensee who opts to resolve outstanding issues with the patent holder rather than pursue prompt pre-license judicial resolution should similarly leave the courts powerless to entertain belated efforts to obtain relief the licensee chose previously to forgo.

In the patent setting, precluding suit when a license remains operative faithfully embodies Professor Borchard's views on the availability of declaratory remedies in patent cases. His treatise's chapter on "Patents" contains a sub-section entitled "Cases or Controversies," which advises that "a patentee's claim of infringement is a condition precedent"

of a declaratory judgment action challenging validity. Edwin Borchard, DECLARATORY JUDGMENTS 807 (2d ed. 1941).[4] This commentary provides the short and complete answer to MedImmune's contention that the Act's drafters could not have imagined that a holder of a valid license lacked an actual case or controversy. Pet. Br. 12, 28-31.

Additional public policy factors weigh decisively in favor of the Federal Circuit rule against declaratory judgment actions by licensees in good standing. For many licenses, the patent granted by the P.T.O. is available for the public to examine in its final form before the parties commence their license negotiations. The prospective licensee thus has the ability to study the patent's claims, including its validity and scope, and to obtain an opinion of counsel. The prospective licensee then makes a business decision weighing the cost of accepting a license and paying royalties against the benefit of

---

[4] Professor Borchard explained at greater length (*id.*; emphases added):

> [I]t seems best to *limit declaratory relief for the infringer to cases in which an adversary claim has been made against him*, though it may, it is believed, apply to an article not yet manufactured but only about to be manufactured. This requirement, present in practically all the adjudicated cases, refutes the fear that patentees might be harassed by prospective infringers and be obliged continually to defend their patents. *The fact that a patentee's claim of infringement is a condition precedent of this type of action* places the matter of adjudication of the patent within the control of the patentee, for, if he wishes to avoid adjudication, he can refrain from making charges of infringement. But having made the charge, he then exposes himself to adjudication. In other words, the mere existence of the patent is not a cloud on title, enabling any apprehensive manufacturer to remove it by suit. *It requires an assertion of right under the patent to place the alleged infringer in gear to join issue and challenge the title.*

eliminating the litigation risk that the patent will be found valid and infringed by the licensee's product. *See* Schlicher, LICENSING INTELLECTUAL PROPERTY at 48.

MedImmune's arguments will shatter the equilibrium in patent license agreements in a disruptive way that unfairly favors patent licensees. Under MedImmune's position, licensors will lose rights to continued royalty payments with no chance of recovering any concessions they made during license negotiations. However, the licensee risks nothing to challenge the patent other than its litigation costs. Even if the challenge fails, the licensee continues to enjoy the same immunities and benefits under the license agreement at the same royalty rate. In contrast to MedImmune's contention, the neutral approach taken by the Federal Circuit in *Gen-Probe, Centocor, Genentech,* and *C.R. Bard, Inc. v. Schwartz,* 716 F.2d 874 (Fed. Cir. 1983) preserves the balance of benefits set forth in license agreements.

Neither MedImmune nor its amici supporters identify any compelling public policy reason to afford patent licensees such a uniquely harmful advantage. In fact, there is no equitable basis to allow licensees to maintain the benefits of their license at the same time that they are trying to take away the rights of the licensor. *See generally* Nellie A. Fisher, *The Licensee's Choice: Mechanics of Successfully Challenging a Patent Under License,* 6 TEX. INTELL. PROP. L.J. 1, 43 (1997) ("the licensee who elects to pay royalties while challenging the patent's validity is in effect 'having its cake and eating it too'"); 4 PAT. L. PERSP. § 6.2[2.-2], at 6-41 ("There is "no reason to let the licensee have the best of both worlds. To do so permits him to litigate validity with total immunity from the normal consequences of a holding that a patent is valid and infringed"); *cf. Kelly v. Kosuga,* 358 U.S. 516, 520-21 (1959) ("[T]he courts are to be guided by the overriding general policy, as Mr. Justice Holmes put it, 'of

preventing people from getting other people's property for nothing when they purport to be buying it.") (quoting *Continental Wall Paper Co. v. Louis Voight & Sons Co.*, 212 U.S. 227, 271 (Holmes, J., dissenting)).

The foregoing applies at a minimum to all existing licenses. Were this Court to reverse the Federal Circuit's bar on declaratory judgment actions by licensees in MedImmune's position, the effects on future licenses would also be harmful. Although the Solicitor General suggests that licensors may include enforceable provisions terminating licenses upon licensee suit, or establishing higher royalty rates upon prevailing in such a suit, there are two fundamental problems with the suggestions. First, even such provisions add to negotiations, thus delaying and increasing the costs of reaching any agreement. Second, the Solicitor General is unwilling to assert that such provisions actually would be enforceable. Without that certainty such provisions are no comfort. Prospective licensors would therefore have a strong incentive, or even be compelled, before entering into a license, to file suit against the potential licensee (perhaps with its consent) and propose the license as a settlement that would then have *res judicata* effect. The remedy of a declaratory judgment should not be made available to produce such waste of judicial and private resources.

Permitting declaratory judgment suits by licensees in good standing would also lead to "a deterioration in business ethics in the patent licensing marketplace." 7 PAT. L. PERSP. § 12.4[6], at 12-123. MedImmune's proposed standard would encourage licensees to enter into license agreements as a pre-litigation tactic affording a safe platform from which to litigate. Operating under the protection of the license, the licensee could then turn around and sue the licensor (who remains bound by the contract) at a time and often in a jurisdiction of the licensee's choosing.

This is not hypothetical – it is precisely the tactic used by MedImmune prior to filing the *Centocor* litigation. There is, accordingly, a real danger that other current and potential licensees will engage in similar conduct if MedImmune's tactics are rewarded by this Court.

Under settled declaratory judgment standards, the adverse consequences for licensors and the resulting danger to the public substantially outweigh the needs of a plaintiff licensee in good standing who is in no danger of being sued. MedImmune offers no valid, supportable principle for rejecting a standard that holds licensees to obligations they voluntarily undertook, while providing a prompt, pre-license (or post-breach) opportunity to litigate patent validity.

CONCLUSION

The judgment should be affirmed.

Respectfully submitted.

RICHARD G. TARANTO
FARR & TARANTO
Suite 800
1220 19th Street, N.W.
Washington, DC 20036-2435

JERROLD J. GANZFRIED
Counsel of Record
JOHN F. STANTON
HOWREY LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 783-0800

TERESA M. CORBIN
JENNIFER A. SKLENAR
HOWREY LLP
525 Market Street, Suite 3600
San Francisco, CA 94105
(415) 848 4900

JULY 26, 2006

APPENDIX

APPENDIX A

LIST OF AMICI CURIAE

THE AMERICAN ASSOCIATION OF MEDICAL COLLEGES

The Association of American Medical Colleges ("AAMC"), founded in 1876, is a private voluntary non-profit association of medical schools, teaching hospitals, health systems, and academic societies. Its membership includes the nation's 126 accredited medical schools, nearly 400 teaching hospitals, and more than 105,000 faculty in 98 academic and scientific societies.

THE ASSOCIATION OF AMERICAN UNIVERSITIES

The Association of American Universities ("AAU") is an organization of research universities devoted to maintaining a strong system of academic research and education. It consists of 60 U.S. universities and two Canadian universities, divided about evenly between public and private. Today, the primary purpose of the AAU is to provide a forum for the development and implementation of institutional and national policies promoting strong programs in academic research and scholarship and undergraduate, graduate, and professional education.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

The Board of Trustees of the Leland Stanford Junior University ("Stanford") is one of a select group of universities that has achieved eminence in both undergraduate and graduate education in a broad range of

academic disciplines. Stanford has more than 6,700 undergraduate students, nearly 8,200 graduate students and nearly 1,800 faculty members. The accomplishments of Stanford faculty member include 15 Nobel laureates, 3 National Medal of Technology recipients, 134 members of the National Academy of Sciences and 82 National Academy of Engineering members. Stanford's Office of Technology Licensing, which is responsible for the issuance of more than 1,500 patents, is guided by the principle of "doing what is best for the technology" which routinely results in licensing for the public benefit.

THE CALIFORNIA INSTITUTE OF TECHNOLOGY

The California Institute of Technology (Caltech) is one of the world's major research centers with an outstanding faculty, including five Nobel Laureates, and a student body of approximately 900 undergraduates and 1000 graduate students in science and engineering. Caltech is consistently among the top three universities that receive United States patents, which it licenses to benefit the public and to fund research.

THE COUNCIL ON GOVERNMENTAL RELATIONS

The Council on Governmental Relations ("COGR") is an association of more than 170 U.S. research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of government regulations, policies, and practices on the performance of research conducted at its member institutions. COGR has a longstanding interest in and concern for assuring the continued effectiveness of the Bayh-Dole Act (P.L. 96-517) and implementing federal regulations (37

C.F.R. 401 et. seq.) in facilitating technology transfer by U.S. universities.

THE NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND-GRANT COLLEGES

The National Association of State Universities and Land-Grant Colleges ("NASULGC") was founded in 1887 and is the nation's oldest higher education association. Its members include public universities, public-university systems, and land-grant institutions from all 50 states, the U.S. territories and the District of Columbia. Many of the top 100 recipients of federal funds for research and development are NASULGC-affiliated institutions.

Much research performed by universities affiliated with NASULGC is directed to core issues at the forefront of basic science. Groundbreaking university research is later developed - through substantial investment by licensees - into products with wide public benefit. NASULGC and its members have an interest in assuring that universities should not be disadvantaged in their patent rights.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

The Regents of the University of California is a public university of ten campuses and five medical schools together with two national laboratories operated by The Regents on behalf of the U.S. Department of Energy. The Regents provide for technology transfer for each site as a part its mission of education, research and public service.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

The Trustees of Columbia University in the City of New York ("Columbia") is a private, nonprofit institution of higher education whose activities are concentrated at two locations in New York City and extend around the globe. Columbia provides instruction through 16 undergraduate, graduate, and professional schools, including one of the largest academic medical centers in the United States, and conducts research, training, and other services under grants and contracts with agencies of the federal government and other sponsoring organizations. Columbia enrolls approximately 23,800 students and employs approximately 12,600 full-time employees, including 4,700 full-time faculty members.

THE UNIVERSITY OF WASHINGTON

The University of Washington is a public research university with campuses in Seattle, Bothell, and Tacoma. It has over 27,600 faculty and staff, and almost 43,000 students. Annually, the University receives almost $1.0 billion in sponsored research support from federal, foundation, and industrial sources.